

Before the **DOCKET FILE COPY ORIGINAL**  
**FEDERAL COMMUNICATIONS COMMISSION**  
Washington, D.C. 20554

In the Matter of )  
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Amendment of Parts 2 and 95 of the )  
Commissions' Rules to Establish The ) RM No. 11271  
Medical Data Service at 401-402 and )  
405-406 MHz )

**ORIGINAL**

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Federal Communications Commission  
Office of Secretary

**COMMENTS OF DEXCOM, INC.**

DexCom, Inc. ("DexCom"), by its attorneys, hereby comments on the above-captioned Petition for Rulemaking ("Petition"). DexCom has no objection to a grant of additional spectrum for use by medical implant devices, although it does not require any additional Medical Implant Communications Service ("MICS") spectrum allocation for the operation of its technologies. DexCom, however, vigorously opposes any change to the rules that would subject certain MICS devices to the miniscule power level requirements proposed in the Petition, and urges the Commission to reject such rule changes.

**INTRODUCTION**

DexCom manufactures a system of blood glucose implant devices that monitor blood glucose data continuously and periodically transmit such data to an external receiver. The system consists of a short-term sensor ("STS"), which is placed in a patient for up to three days and then replaced, and a long-term sensor ("LTS"), which is placed in a patient for up to one year. Studies have shown that the DexCom system is highly effective in allowing diabetics to manage their blood glucose levels and thus avoid the terrible complications of diabetes. DexCom expects to receive FDA approval shortly and to begin to market its system soon after.

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DexCom's system, however, cannot operate without a waiver of the Commission's MICS rules, and DexCom has applied for such a waiver.<sup>1</sup> Under the present MICS rules, DexCom's devices cannot be manufactured to comply with the listen-before-transmit requirements. Although DexCom has applied for waiver of the MICS rules, it urges the Commission to consider amending the rules to allow for more flexibility with regard to the listen-before-transmit requirement.

## DISCUSSION

The Petition would create two tiers of medical implant devices – separate and unequal – in which devices that do not have listen-before-transmit technology would have to operate on new spectrum at low power and duty cycle levels.<sup>2</sup> The stated reasons for the proposed bifurcation of medical implant devices are not supported, as there is no crowding in the MICS band and no harmful interference problems have been reported. DexCom believes that the Commission should proceed with its own rulemaking to change the present MICS rules and foster a greater variety of implantable medical devices for use by the public.

DexCom does not oppose grant of additional spectrum for MICS. DexCom, however, can operate its technology within the existing allocation for the MICS band. DexCom does strongly object to any change in the MICS rules that would require certain MICS devices to operate at the low power level proposed in the Petition. The Medtronic proposal would require devices that cannot meet the MICS listen-before-transmit requirements, such as DexCom's system, to operate on newly allocated spectrum under extremely low power levels not to exceed 250 nanowatts EIRP. The DexCom system cannot meet such a restrictive power level requirement. The DexCom system operates at just under the 25 microwatts maximum power level allowed under

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<sup>1</sup> See *In the Matter of DexCom Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules*, Request for Waiver, ET Docket No. 05-213 (filed May 23, 2005)

<sup>2</sup> Petition at 11.

the MICS rules. DexCom requires this power level to achieve the range needed to transmit up to five (5) feet away from the receiver. This range is necessary so that patients can lead normal lives by, for example, being able to lie on the sensor while asleep or to shower with the receiver placed outside the shower stall.

The proposed rules would unnecessarily subject certain MICS devices to overly stringent power level requirements. For example, the proposed power level would be 100 times less than the power needed for DexCom's system. Reducing the output power of the system transmitter would severely restrict the range needed for proper operation. Reduction of power by 100 times (or 20 dB) would leave the DexCom system with no fade margin and very little allowance for antenna polarization losses. This means that if a patient turns over onto the sensor during sleep, for example, the data would not be able to conduct through the patient's body to the handheld receiver placed nearby.

Further, it would be years before the suggested new MEDS band were approved by the FCC, assuming such approval ever would occur. Patients cannot wait that long to have access to medical implant devices.

## **CONCLUSION**

The Commission should deny the Petition to the extent it would force MICS devices to move to new spectrum and operate under unduly restrictive power levels. DexCom urges the Commission to initiate its own rulemaking proceeding to consider expanding MICS by providing for greater flexibility in the listen-before-transmit requirements.

Respectfully submitted,  
DEXCOM, INC.

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September 23, 2005

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing Comments of DexCom, Inc. was sent by first-class mail, postage prepaid, this 23rd day of September, 2005, to the following:

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Brenda Campbell